

Practitioner's Docket No. MWH-0425US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Chew, Anne et al.,

Application No.: To be assigned
Filed: November 14, 2001

Group No.: To be assigned
Examiner: To be assigned

For: Haplotypes of the ICAM2 Gene

Assistant Commissioner for Patents
Washington, D.C. 20231
ATTENTION: Group Director, Group 1600

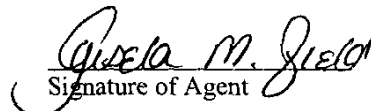
TRANSMITTAL

Enclosed herewith please find:

1. A supplement to the Petition for Accelerated Examination of New Application (1 page)
2. A Copy of the International Search Report
3. Copies of the 5 References Cited
4. A self-addressed stamped postcard

It is believed that no fee is required, but if that is incorrect, you are hereby authorized to debit deposit account 50-1293 for any deficiency. A duplicate copy of this Transmittal is attached.

Date: 11/15/01

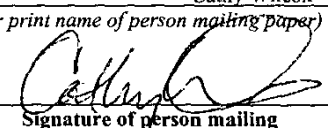

Signature of Agent

Reg. No.: 47,562
Tel. No.: 203-786-3473

Gisela Field
Genaissance Pharmaceuticals, Inc.
Five Science Park
New Haven, CT 06511
USA

CERTIFICATION UNDER 37 C.F.R. SECTION 1.10*
(Express Mail label number is **mandatory**.)
(Express Mail certification is optional.)

I hereby certify that this correspondence and the documents referred to as attached therein are being deposited with the United States Postal Service on Nov. 19, 2001 (date), in an envelope as "EXPRESS MAIL POST OFFICE TO ADDRESSEE" service under 37 C.F.R. Section 1.10, Mailing Label Number EL594594366US addressed to Box PCT, Assistant Commissioner for Patents, Washington, D.C. 20231.

Cathy Wilcox
(type or print name of person mailing paper)

Signature of person mailing

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SUPPLEMENT TO THE PETITION FOR ACCELERATED EXAMINATION OF NEW APPLICATION
(37 C.F.R. 1.102 and M.P.E.P. 708.02 VIII)


On November 14, 2001, a Petition for Accelerated Examination of New Application was submitted along with a Transmittal Letter to the United States DO/EO Concerning a Filing Under 35 U.S.C. 371. As part of the requirements for filing the petition, a copy of the International Search Report and all cited references must be attached. Applicants stated on page 1 of the petition filed November 14, 2001 that such documents were attached but inadvertently forgot to send them along with the filing. Thus, attached here in this submission is a copy of the International Search Report mailed by the International Searching Authority/US on September 27, 2001 along with a copy of the 5 cited references. Applicants believe that the requirements set forth in MPEP 708.02 VIII are now satisfied and review of the petition is respectfully requested. A copy of the original petition as filed is also attached.

Should any questions arise, or if Applicant or Applicant's Agent can facilitate examination of this application, it is respectfully requested that the undersigned Agent be contacted so that any remaining issues can be resolved.

Respectfully submitted,

11/15/01

Reg. No. 47,562
Tel. No. 203-786-3473


Gisela M. Field
Genaissance Pharmaceuticals, Inc.
Five Science Park
New Haven, CT 06511

#3
Rec'd PCT/PTU 14 NOV 2001

09/979593

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PATENT

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For: Haplotypes of the ICAM2 Gene

Assistant Commissioner for Patents
Washington, D.C. 20231
ATTENTION: Group Director, Group 1600

PETITION FOR ACCELERATED EXAMINATION OF NEW APPLICATION
(37 C.F.R. 1.102 and M.P.E.P. 708.02 VIII)

1. Petition

Applicant hereby petitions to make this application special.

2. Statement that all claims are directed to a single invention

All the claims of the present application relate to the discovery of how polymorphisms for a particular set of twelve polymorphic sites in the intercellular adhesion molecule 2 (ICAM2) gene are organized into haplotypes that define different naturally-occurring variants of the ICAM2 gene. In addition, the International Searching Authority did not make any indication that multiple inventions were claimed in the present application. Thus, it is respectfully submitted that all claims are directed to a single invention.

3. Statement of Pre-Examination Search

Attached is a copy of the International Search Report mailed by the International Searching Authority/US on September 27, 2001, which satisfies the pre-examination search requirement as set forth in MPEP 708.02 VIII (c). The following fields were searched: 435/325; 536/23.1, 23.5; and 800/3, 13 in addition to the following databases: STN (CAPlus, biosisi, medline) and EAST.

4. Copies of References

Attached is a copy of each of the five references that are cited in the International Search Report.

5. Statement Discussing Cited References

Attached is a statement by the Agent that discusses the cited references and points out how the invention is novel and non-obvious over these references.

6. Fee

The fee of \$130.00 as required by 37 CFR 1.17(i) is to be paid by Deposit Account No. 50-1293. A duplicate copy of this petition is attached.

**DISCUSSION OF REFERENCES PURSUANT TO PETITION TO MAKE SPECIAL
UNDER CFR 1.102 AND MPEP 708.02 VIII**

Claims 1-33 in the present application are directed to methods and compositions relating to a set of twelve polymorphic sites in the human ICAM2 gene at nucleotide positions 74697 (PS1), 75110 (PS2), 75141 (PS3), 75221 (PS4), 76302 (PS5), 78155 (PS6), 78181 (PS7), 78187 (PS8), 78875 (PS9), 78902 (PS10), 78961 (PS11), and 79037 (PS12) and to haplotypes comprised of these sites. Three of the cited references (Kuramoto et al., Gerwin et al., and Sultan et al.,) discuss mutations in the **mouse** ICAM2 gene. The present application relates to discoveries in the **human** ICAM2 gene. In addition, none of these cited references, either singularly or in combination with each other, suggest the use of or disclose any human ICAM2 polymorphisms or haplotypes. The other two cited references, Akella et al., and US Patent 5,489,533 also do not disclose any human ICAM2 polymorphisms or haplotypes. While US Patent 5,489,533 discusses functional derivatives of the ICAM2 gene as including variants of the gene, no specific nucleic or amino acid variants are disclosed in the specification and the claims of this patent are not directed to compositions or methods of any such ICAM2 functional derivatives. In addition, this patent does not suggest the use of ICAM2 functional derivatives in methods of haplotyping, genotyping or in compositions of the present application. In conclusion, applicants respectfully submit that none of the references cited in the International Search report, either singularly or in combination, suggest the use of or disclose methods or compositions relating to human ICAM2 haplotypes or polymorphisms and that claims 1-33 are patentable over the cited references.

PATENT COOPERATION T TY

From the INTERNATIONAL SEARCHING AUTHORITY

To: GISELA M. FIELD
BENAISSANCE PHARMACEUTICALS, INC.
FIVE SCIENCE PARK
NEW HAVEN, CT 06511

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT
OR THE DECLARATION

(PCT Rule 44.1)

Date of Mailing (day/month/year) 27 SEP 2001	
Applicant's or agent's file reference MWH-0425PCT	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/US01/14714	International filing date (day/month/year) 07 MAY 2001
Applicant GENAISSANCE PHARMACEUTICALS, INC.	

1. ☒ The applicant is hereby notified that the international search report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the international search report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet..

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in rules 90 bis 1 and 90 bis 3, respectively, before the completion of the technical preparations for international publication.

Within 19 months from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within 20 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer JOSEPH T. WOITACH
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0196

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference MWH-0425PCT	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. PCT/US01/14714	International filing date (day/month/year) 07 MAY 2001	(Earliest) Priority Date (day/month/year) 05 MAY 2000
Applicant GENAISSANCE PHARMACEUTICALS, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
- b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing:
- ☒ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.
2. ☐ Certain claims were found unsearchable (See Box I).
3. ☐ Unity of invention is lacking (See Box II).
4. With regard to the title,
- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established by this Authority to read as follows:
5. With regard to the abstract,
- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.
6. The figure of the drawings to be published with the abstract is Figure No. _____
- ☐ as suggested by the applicant.
- ☐ because the applicant failed to suggest a figure.
- ☐ because this figure better characterizes the invention.
- ☒ None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/14714

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : C12N 5/00; C07H 21/02, 21/04; G01N 33/00; A01K 67/00

US CL : 435/325; 536/23.1, 23.5; 800/3, 13

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 435/325; 536/23.1, 23.5; 800/3, 13

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Sequence search of commercial databases for SEQ ID NOs in Figure 1; STN (CAPLus, biosisi, medline); EAST

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,489,533 A (SPRINGER et al.) 06 February 1996, figures 2 and 4 and Table 1.	1-31
Y	KURAMOTO, T. et al. The alymphoplasia (aly) mutation co-segregates with the intercellular adhesion molecule-2 (Icam-2) on mouse chromosome 11. International Immunology. July 1994. Vol. 6. No. 7. pages 991-994, especially Table 1.	1-31

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

-	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance		
"E"	earlier document published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed	"G"	document member of the same patent family

Date of the actual completion of the international search

07 AUGUST 2001

Date of mailing of the international search report

27 SEP 2001

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

JOSEPH T. WOITACH

Telephone No. (703) 308-0196

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/14714

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	AKELLA, R. et al. Expression of the adhesion molecules ICAM-1 and ICAM-2 on tumor cell lines does not correlate with their susceptibility to natural killer cell-mediated cytotoxicity: evidence for additional ligands for effector cell beta 2 integrins. European Journal of Immunology. April 1992. Vol 22. No. 4. page 1069-1074, especially pages 1071-1073.	1-31
Y	GERWIN, N. et al. Prolonged eosinophil accumulation in allergic lung interstitium of ICAM-2-deficient mice results in extended hyperresponsiveness. Immunity. January 1999. Vol 10. No. 1. pages 9-19, especially Figure 1 and methods section.	1-31
Y	SULTAN, A. et al. Sporozoites of Plasmodium yoelii mice with targeted deletions in ICAM-1 and ICAM-2 or complement components C3 and C4. Molecular and Biochemical Parasitology. September 1997. Vol 88. No. 1-2. pages 263-266, entire reference.	1-31